IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Hilaly *et al.*

Appl. No. 10/824,358

Filed: April 15, 2004

For: **Process for Producing High Purity Isoflavones**

Confirmation No. 6313

Art Unit: 1761

Examiner: Anthony J. Weier

Atty. Docket: 1533.6040002

Declaration of Ahmad K. Hilaly, Bob Sandage and John Soper Under 37 C.F.R. § 1.131

Commissioner for Patents
Washington, D.C. 20231

Sir:

The undersigned, Ahmad K. Hilaly, Bob Sandage and John Soper, declare and state that,

1. We are the inventors of the above-captioned application, U.S. Appl. No. 10/824,358, filed April 15, 2004 (the "'358 application"). We are also the inventors of U.S. Appl. No. 10/409,683, filed April 9, 2003 ("'683 application"), and U.S. Provisional Patent Appl. No. 60/271,129 (the "'129 application"), filed on April 10, 2002.

2. The '358 application is a divisional application of the '683 application, which claims the benefit of the '129 application.

3. Prior to January 9, 2002, we, the inventors, had conceived of our invention in the United States, as claimed in the subject application, and diligently proceeded to file a patent application as evidenced by the following:

4. Exhibit A is twelve (12) pages of a dated document (date redacted) showing data from isoflavone purification experiments that generally correspond to the pending application, and which represent examples of the claimed invention. Exhibit A was prepared by us prior to January 9, 2002. This is earlier than the publication date of Izumi *et al.*, Japanese Patent Application No. P2002-184802A (January 9, 2002) and the publication date of Katayama *et al.*, Japanese Patent Application No. P2002-80474A (March 19, 2002).

5. We began the protocol that results in the high purity isoflavone enriched fraction of claimed invention prior to January 9, 2002. High purity isoflavone enriched fractions were prepared between August and November, 2001. An invention disclosure form was submitted to our legal department and the above-mentioned provisional application was filed April 10, 2002.

6. As the persons signing below, we hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issue thereupon.

11-17-04 — Ahmad Hilaly
Date — Ahmad K. Hilaly

11-18-04 — Robert Sandage
Date — Bob Sandage

11/17/04 — John Soper
Date — John Soper

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ISOFLAVONE pH VS. ADSORBTION TESTS

THE PURPOSE OF THESE TESTS IS TO ASSESS THE PERFORMANCE OF OTHER ANIONIC RESINS IN OUR ISOFLAVONE PROCESS. THESE WILL BE OUR STANDARD S AD TESTS

EXPERIMENTAL DATA

EXPERIMENT NUMBER: 67A
FEED: pH ADJUSTED @ PLANT // 100K MWCO // PLANT U/F PERM. (GMO FEED)
COND'S: pH 8.95
CONDITIONS: FEED RATE: 12 MLS/MIN
COLUMN TEMP.: 60 DEG C
RESIN: 12A MP (PLANT RESIN)
DATE: 6/8/01 LOADING: 11.765 g/L resin BED VOLUME: 100 mls
ISOFLAVONE CONC. IN FEED: 1176.47 PPM
ISOFLAVONE CONC. IN FEED: 1.176 g/L
BED VOLUMES FED: 10 B.V.

	Volume (L)	Isoflavone (mg/kg)	D/S (g/kg)	Vol/g	Purity %	Yield %	
FEED	10	1176	80.9		0.3	100.00	
RAFFINATE	1.0	331.2	138.8		0.2	28.15	38.17
RINSE NO. 1	0.3	393.0	39.0		1.0	10.02	
PRODUCT	1.0	2195.9	3.0		72.4	186.65	
PRODUCT 2X		1194.4	1.7		71.4	0.00	
RINSE NO. 2	0.3	32.4	0.4		8.1	0.85	
2.5% CAUSTIC	0.25	135.6	22.2		0.6	2.86	
RINSE NO. 3	0.5	9.0	9.0		0.1	0.23	
CAUS						220.76	

EXPERIMENT NUMBER: 67B
FEED: pH ADJUSTED @ PLANT // 100K MWCO // PLANT U/F PERM. (GMO FEED)
COND'S: pH : 8.95
CONDITIONS: FEED RATE: 12 MLS/MIN
COLUMN TEMP.: 60 DEG C
RESIN: MITSUBISHI SAP 12A
LOADING: 11.765 g/L resin BED VOLUME: 100 mls
ISOFLAVONE CONC. IN FEED: 1176.47 PPM
ISOFLAVONE CONC. IN FEED: 1.176 g/L
BED VOLUMES FED: 10 B.V.

	Volume (L)	Isoflavone (mg/kg)	D/S (g/kg)	Vol/g	Purity %	Yield %
FEED	10	1176	80.9		0.3	100.00
RAFFINATE	10	344.5	134.5		0.1	28.28
RINSE NO. 1	0.3	339.56	36.0		0.9	8.67
PRODUCT	0.5	711.08	1.4		50.1	30.22
PRODUCT 2X		353.45	0.7		53.4	0.00
RINSE NO. 2	0.3	137.24	1.3		10.7	3.50
2.5% CAUSTIC	0.25	41.81	22.8		0.2	0.89
RINSE NO. 3	0.3	6.0	8.0		0.1	0.15

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Witnessed and Understood by Me	Date	Recorded/Invented by	Date
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ISOFLAVONE pH VS. ADSORBTION TESTS

THE PURPOSE OF THESE EXPERIMENTS IS TO A.) FOLLOW THE PILOT C-SEP TO ASCERTAIN SYSTEM PERFORMANCE VS. SINGLE COLUMN; AND B.) TO FURTHER TEST THE SAF 12A RESIN FROM MITSUBISHI FOR USE IN THIS PROCESS.

EXPERIMENTAL DATA

EXPERIMENT NUMBER: 68A FEED: pH ADJUSTED @ PLANT // 100K MWCO // PLANT U/F PERM. (GMO FEED)

COND'S: pH 9.0

CONDITIONS: FEED RATE: 12 MLS/MIN

COLUMN TEMP.: 60 DEG C

RESIN: A-2X MP (PLANT RESIN)

DATE: 8/9/04 LOADING: 1129.59 g/L resin BED VOLUME: 100 mls

ISOFLAVONE CONC. IN FEED: 1129.59 PPM

ISOFLAVONE CONC. IN FEED: 1.130 g/L

BED VOLUMES FED: 10 B.V.

	Volume (L)	Isoflavone (mg/kg)	D/S (g/kg)	Vol./g	Purity %	Yield %
FEED	1.0	1129.6	100.2		1.1	100.00
RAFFINATE	10.0	362.0	92.9		6.2	29.22
RINSE NO. 1	0.3	378.8	34.2		1.1	10.05
PRODUCT	1.0	1683.5	2.5		67.8	149.03
PRODUCT 2X		876.0	1.1		53.0	0.00
RINSE NO. 2	0.3	28.9	0.1		28.9	0.77
2.5% CAUSTIC	0.25	136.8	121.6		0.1	3.03
RINSE NO. 3	0.3	21.5	77.2		0.0	0.57
					TOTAL	192.46

EXPERIMENT NUMBER: 68B FEED: pH ADJUSTED @ PLANT // 100K MWCO // PLANT U/F PERM. (GMO FEED)

COND'S: pH 9.0

CONDITIONS: FEED RATE: 12 MLS/MIN

COLUMN TEMP.: 60 DEG C

RESIN: MITSUBISHI SAF 12A

DATE: 8/9/04 LOADING: 1129.59 g/L resin BED VOLUME: 100 mls

ISOFLAVONE CONC. IN FEED: 1129.59 PPM

ISOFLAVONE CONC. IN FEED: 1.130 g/L

BED VOLUMES FED: 10 B.V.

	Volume (L)	Isoflavone (mg/kg)	D/S (g/kg)	Vol./g	Purity %	Yield %
FEED	1.0	1129.6	100.2		1.1	100.00
RAFFINATE	10.0	1662.1	91.9		0.8	14.72
RINSE NO. 1	0.3	266.9	29.7		10.3	7.09
PRODUCT	0.5	351.2	1.2		45.6	24.40
PRODUCT 2X		261.3	0.3		74.7	0.00
RINSE NO. 2	0.3	183.7	1.1		15.5	4.36
2.5% CAUSTIC	0.25	63.8	97.1		0.1	1.41
RINSE NO. 3	0.3	11.9	45.6		0.0	0.32
					TOTAL	52.28

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Witnessed and Understood by Me	Date	Recorded/Invented by	Date
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ISOFLAVONE pH VS. ADSORBTION TESTS

THE PURPOSE OF THESE EXPERIMENTS IS TO: A.) DETERMINE THE EFFECT OF RUNNING STRIPPER PRODUCT THROUGH AS A RINSE (A, AND B.) DETERMINE THE FEASABILITY OF RUNNING OUR STRIPPER PRODUCT THROUGH THE RESIN AGAIN, TO INCREASE PURITY.... STRIPPER PRODUCT IS C-SEP PRODUCT (FROM THE PLANT) THAT HAS HAD THE ETHANOL REMOVED.

EXPERIMENTAL DATA

EXPERIMENT NUMBER: 70A FEED: pH ADJUSTED C-PLANT // 100K MWCO // PLANT D/F PERM. (GMO FEED)

CONDITIONS: COND'S: pH 6.7
FEED RATE: 12 MLS/MIN
COLUMN TEMP.: 60 DEG C
RESIN: A-2X-MP (PLANT RESIN)

DATE: 11/3/04 LOADING: 3.600 gr/L resin BED VOLUME: 100 mls
ISOFLAVONE CONC. IN FEED: 1090.9 mg/L ISOFLAVONE CONC. IN FEED: 1.091 g/L STRIPPER PROD. 969.1 mg/kg Isoflavones
BED VOLUMES FED: 10 B.V.

	Volume (L)	Isoflavone (mg/kg)	D/S (g/kg)	Vol./g	Purity %	Yield %
FEED	1.0	1090.9	89.1		1.2	100.00
RAFFINATE	1.0	275.9	80.7		0.3	22.77
STRP. PROD RINSE (A)	0.3	447.2	22.5		2.0	10.65
DI RINSE (B)	0.3	283.1	1.2		23.6	6.24
PRODUCT	1.0	1722.5	5.4		60.8	140.66
PRODUCT 2X		864.9	1.7		49.5	0.00
RINSE NO. 2	0.3	46.2	0.4		12.8	1.13
2.5% CAUSTIC	0.25	241.6	23.6		1.0	4.93
RINSE NO. 3	0.3	22.1	9.1		0.2	0.54
					TOTAL	97.33

EXPERIMENT NUMBER: 70B FEED: STRIPPER PRODUCT

CONDITIONS: COND'S: pH ADJUSTED TO 9.55; 2L OF STRIP. PROD. DILUTED WITH 2L OF DI H2O
FEED RATE: 12 MLS/MIN
COLUMN TEMP.: 60 DEG C
RESIN: A-2X-MP (PLANT)

LOADING: 3.691 gr/L resin BED VOLUME: 100 mls
ISOFLAVONE CONC. IN FEED: 969.12 PPM
ISOFLAVONE CONC. IN FEED: 0.969 g/L
BED VOLUMES FED: 10 B.V.

	Volume (L)	Isoflavone (mg/kg)	D/S (g/kg)	Vol./g	Purity %	Yield %
FEED	1.0	969.1	2.3		41.7	100.00
RAFFINATE	1.0	11.4	0.6		1.9	1.181
RINSE NO. 1	0.3	47.0	0.3		15.6	1.45
PRODUCT	0.5	293.2	1.5		56.2	65.21
PRODUCT 2X		582.3	0.8		75.9	0.00
RINSE NO. 2	0.3	82.1	0.2		32.8	2.54
2.5% CAUSTIC	0.25	47.0	23.2		0.2	1.21
RINSE NO. 3	0.3	6.5	9.4		0.1	0.21
					TOTAL	71.80

Witnessed and Understood by Me	Date	Recorded/Invented by	Date
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ISOFLAVONE HIGH PURITY STEP WISE ELUTION TESTS

THE PURPOSE OF THESE EXPERIMENTS IS TO DETERMINE IF RESINS, (ADS 600 & DCA-1), GIVE A HIGHER PURITY PRODUCT FROM PLANT FINAL PRODUCT UTILIZING A GRADIENT ELUTION OF 95% ETOH FOLLOWED BY A 70% ELUTION WASHING

EXPERIMENTAL DATA DATE: 10/18/01

EXPERIMENT NUMBER 3 FEED: PLANT FINAL PRODUCT (DILUTED 4gm WITH 2L DI H2O PH to 9.3) HEATED TO 70 C

COND'S pH "ADJUSTED" 9.7

CONDITIONS FEED RATE 12 ML/MIN
COLUMN TEMP 65 DEG C
RESIN ADS 600

D/S

DATE: 10/18/01 LOADING: 7.507 g/L resin BED VOLUME 100 mls
ISOFLAVONE CONC. IN FEED: 3361.50 PPM
ISOFLAVONE CONC. IN FEED: 0.362 g/L
BED VOLUMES FED: 18 B.V.

	Volume (L)	Isoflavons(mg/kg)	D/S(g/kg)	Vol/g	Purity %	Yield %	D/S Account.
FEED	1.8	361.8	2.4		15.1	100.00	100.00
RAFFINATE	1.5	22.9	4.8		0.5	6.33	200.00
RINSE NO 1	0.3	26.3	0.5		5.3	1.21	3.47
COMPOSITE(1st 3 fracts) 35%	0.3	1663.0	6.9		52.9	168.42	47.92
PRODUCT 2X		1560.0	9.9		15.8	0.00	0.00
COMPOSITE(all 5 fracts) 35%	0.5	2725.0	11.3		50.5	125.26	62.50
PRODUCT 2X		1343.8	9.0		14.9	0.00	0.00
COMPOSITE 70%	0.5	12.6	0.8		1.8	0.97	9.26
PRODUCT 2X		6.9	1.4		0.5	0.00	0.00
RINSE NO. 2	0.3	0.8	1.2		0.1	0.04	8.33
2.5% CAUSTIC	0.3	1.5	84.2		0.0	0.06	480.56
RINSE NO 3	0.3	2.0	108.5		0.0	0.09	759.58
					TOTAL	226.00	1503.72

FREEZE DRIED RESULTS (FROM 1ST 3 FRACTIONS)

Total Isoflav.,ppm	Daidzin, ppm	Genistin, ppm	Ratio
340.8	175256	311726	0.60

EXPERIMENT NUMBER 4 FEED: PLANT FINAL PRODUCT (DILUTED 4gm WITH 2L DI H2O PH to 9.3) HEATED TO 70 C

COND'S. pH "ADJUSTED" 9.3

CONDITIONS FEED RATE 12 ML/MIN
COLUMN TEMP 65 DEG C
RESIN DCA-1

LOADING: 6.507 g/L resin BED VOLUME: 100 mls
ISOFLAVONE CONC. IN FEED: 3361.50 PPM
ISOFLAVONE CONC. IN FEED: 0.362 g/L
BED VOLUMES FED: 18 B.V.

	Volume (L)	Isoflavons(mg/kg)	D/S(g/kg)	Vol/g	Purity %	Yield %	D/S Account.
FEED	1.8	361.5	2.4		15.1	100.00	100.00
RAFFINATE	1.5	22.9	4.8		0.7	1.63	140.00
RINSE NO 1	0.3	48.1	0.4		1.2	0.22	1.25
COMPOSITE(1st 3 fracts) 35%	0.3	1778	3.4		52.1	91.74	25.61
PRODUCT 2X		815.4	1.0		81.5	0.00	0.00
COMPOSITE(all 5 fracts) 35%	0.5	1874.1	3.0		62.5	144.01	34.72
PRODUCT 2X		910.9	1.2		75.9	0.00	0.00
PRODUCT(70%)	0.5	721.6	1.0		72.2	55.45	11.57
PRODUCT 2X		375.6	0.4		93.9	0.00	0.00
RINSE NO. 2	0.3	18.8	0.0		0.0	0.77	0.00
2.5% CAUSTIC	0.3	15.5	0.0		0.0	0.74	5.79
RINSE NO 3	0.3	8.7	0.0		0.0	0.74	9.46
					TOTAL	203.54	1606.02

FREEZE DRIED RESULTS (FROM 1ST 3 FRACTIONS)

Total Isoflav.,ppm	Daidzin, ppm	Genistin, ppm	Ratio
391605	199606	134624	0.68

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Witnessed and Understood by Me	Date	Recorded/Invented by	Date
	10-19-01	Robert Lansing	[redacted]

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ISOFLAVONE HIGH PURITY STEP-WISE ELUTION TESTS

THE PURPOSE OF THESE EXPERIMENTS IS TO
DETERMINE IF RESINS, (ADS 600, SD-2 & SP-850) GIVE A HIGHER PURITY PRODUCT FROM A DISSOLVED FINAL DRY PRODUCT UTILIZING A STEP-WISE ELUTION OF 35% ETOH FOLLOWED BY A 70% ELUTION WASHING

EXPERIMENTAL DATA — DATE [illegible]

EXPERIMENT NUMBER 5 — FEED: PLANT FINAL PRODUCT (DILUTED 4gm WITH 2L DI H2O PH to 9.0)

CONDITIONS: FEED RATE 12 MLS/MIN; COLUMN TEMP 60 DEG C; CONDS. pH ADJUSTED 9.5; RESIN ADS 600

D/S

LOADING 13.2 g/L resin — BED VOLUME 100 mls
ISOFLAVONE CONC IN FEED 692.8 PPM
ISOFLAVONE CONC IN FEED 0.69 g/L
BED VOLUMES FED 19 BV

	Volume (L)	Isoflavone(mg/kg)	D/S(g/kg)	Vol/g	Purity %	Yield %	D/S Account
FEED	1.9	692.8	1.9		36.5	100.0	100.0
RAFFINATE	1.9	17.6	[illegible]		[illegible]	[illegible]	62.6
RINSE NO 1	[illegible]	27.5	[illegible]		[illegible]	[illegible]	5.0
PRODUCT(35%)	[illegible]	[illegible]	4.5		[illegible]	[illegible]	[illegible]
PRODUCT 2X	[illegible]	1000.3	2.3		[illegible]	[illegible]	0.0
PRODUCT(70%)	0.5	62.2	0.1		0.0	2.4	1.4
PRODUCT 2X		32.9	0.1		0.0	0.0	0.0
RINSE NO 2	0.3	2.8	0.0		0.0	0.1	0.0
2.5% CAUSTIC	0.3	1.6	48.7		0.0	0.0	197.0
RINSE NO 3	0.3	2.2	67.6		0.0	0.1	501.6
					TOTAL	100.0	877.5

EXPERIMENT NUMBER 6 — FEED: PLANT FINAL PRODUCT (DILUTED 4gm WITH 2L DI H2O PH to 9.0)

CONDITIONS: FEED RATE 12 MLS/MIN; COLUMN TEMP. 60 DEG C; CONDS. pH ADJUSTED 9.0; RESIN SD-2

D/S

LOADING 13.86 g/L resin — BED VOLUME 100 mls
ISOFLAVONE CONC IN FEED 692.8 PPM
ISOFLAVONE CONC IN FEED 0.69 g/L
BED VOLUMES FED 20 B.V.

	Volume (L)	Isoflavone(mg/kg)	D/S(g/kg)	Vol/g	Purity %	Yield %	D/S Account
FEED	1.9	692.8	[illegible]		[illegible]	100.0	100.0
RAFFINATE	1.9	[illegible]	[illegible]		0.9	2.5	[illegible]
RINSE NO 1	0.3	2.2	[illegible]		[illegible]	[illegible]	2.5
PRODUCT(35%)	0.5	1501.2	[illegible]		[illegible]	97.0	50.0
PRODUCT 2X		733.5	1.2		61.1	0.0	0.0
PRODUCT(70%)	0.3	1167.7	1.2		88.0	45.1	10.0
PRODUCT 2X		603.1	0.7		86.2	0.0	0.0
RINSE NO 2	0.3	58.9	0.2		29.5	1.2	1.7
2.5% CAUSTIC	0.3	21.6	52.0		0.0	0.5	226.4
RINSE NO 3	0.3	15.2	53.1		0.0	0.5	401.1
					TOTAL	104.3	803.9

EXPERIMENT NUMBER 7 — FEED: PLANT FINAL PRODUCT (DILUTED 4gm WITH 2L DI H2O PH to 9.0)

CONDITIONS: FEED RATE 12 MLS/MIN; COLUMN TEMP 65 DEG C; CONDS. pH ADJUSTED [illegible]; RESIN: SP-850

D/S

LOADING 13.16 g/L resin — BED VOLUME 100 mls
ISOFLAVONE CONC IN FEED 692.8 PPM
ISOFLAVONE CONC IN FEED 0.69 g/L
BED VOLUMES FED 19 B.V.

	Volume (L)	Isoflavone(mg/kg)	D/S(g/kg)	Vol/g	Purity %	Yield %	D/S Account
FEED	1.9	692.8	[illegible]		[illegible]	100.0	100.0
RAFFINATE	1.9	12.1	1.4		[illegible]	[illegible]	73.7
RINSE NO. 1	0.3	5.6	0.7		0.8	0.1	5.0
PRODUCT(35%)	0.5	2046.7	4.0		51.1	77.7	80.4
PRODUCT 2X		1110.1	2.2		50.5	0.0	0.0
PRODUCT (70%)	0.5	257.2	0.2		[illegible]	9.6	2.6
PRODUCT 2X		150.1	0.0		0.0	0.0	0.0
RINSE NO 2	0.3	0.9	0.1		0.8	0.0	0.6
2.5% CAUSTIC	0.3	11	63.6		0.0	0.0	320.6
RINSE NO 3	0.3	12	40.5		0.0	0.0	236.6
					TOTAL	[illegible]	79[illegible]

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ISOFLAVONE HIGH PURITY STEP-WISE ELUTION TESTS

THE PURPOSE OF THESE EXPERIMENTS IS TO DETERMINE IF RESINS (ADS 600,DCA-11 & SP-850) GIVE A HIGHER PURITY PRODUCT FROM PLANT STRIPPER PRODUCT DILUTED WITH DI H2O & pH ADJUSTED UTILIZING A STEP-WISE ELUTION OF 35% ETOH FOLLOWED BY A 70% ELUTION WASHING

EXPERIMENTAL DATA — DATE 11/22/00

EXPERIMENT NUMBER 8 — FEED PLANT STRIPPER PRODUCT (DILUTED 1:3 WITH DI H2O)

CONDITIONS: COND'S pH "ADJUSTED" 9.3; FEED RATE 12 ML/MIN; COLUMN TEMP 65 DEG C; RESIN ADS 600; 0.152 D/S

LOADING 13.622 g/L resin — BED VOLUME 100 mls

ISOFLAVONE CONC IN FEED 681.10 PPM

ISOFLAVONE CONC IN FEED 0.091 g/L

BED VOLUMES FED 30 B.V

	Volume (L)	Isoflavone(mg/kg)	D/S(g/kg)	Vol/g	Purity %	Yield %	D/S Accepted
FEED	2.0	681.1	19		15.6	100.00	100.00
RAFFINATE	2.0	7.6	0.6		1.2	37.24	6.31
RINSE NO.1	0.5	62	0.5		5.2	2.28	2.63
PRODUCT (35%)	0.5	21001	3.7		60.02	77.00	19.50
PRODUCT 2X (35%)		13691	2.2		63.2	0.00	0.00
PRODUCT (70%)	0.5	314	0.0		0.0	1.15	0.00
PRODUCT 2X (70%)		171	0.0		0.0	0.00	0.00
RINSE NO.2	0.5	71	0.0		0.0	0.16	0.00
2.5% CAUSTIC	0.5	57	49.1		0.0	0.13	166.26
RINSE NO.3	0.5	7.6	14.3		0.1	0.16	112.63
					TOTAL	68.55	572.11

EXPERIMENT NUMBER 9 — FEED PLANT STRIPPER PRODUCT (DILUTED 1:3 WITH DI H2O)

CONDITIONS: COND'S pH "ADJUSTED" 9.3; FEED RATE 12 ML/MIN; COLUMN TEMP 65 Deg C; RESIN SP 850; 0.152 D/S

LOADING 13.620 g/L resin — BED VOLUME 100 mls

ISOFLAVONE CONC IN FEED 681.10 PPM

ISOFLAVONE CONC IN FEED 0.091 g/L

BED VOLUMES FED 30 B.V

	Volume (L)	Isoflavone(mg/kg)	D/S(g/kg)	Vol/g	Purity %	Yield %	D/S Accepted
FEED	2.0	681.1	19		15.6	100.00	100.00
RAFFINATE	2.0	7.6	0.6		1.2	37.24	6.31
RINSE NO.1	0.5	147	0.6		2.5	0.32	2.74
PRODUCT (35%)	0.5	21475	4.0		61.2	69.84	52.63
PRODUCT 2X (35%)		12702	1.9		68.9	0.00	0.00
PRODUCT (70%)	0.5	178.6	0.4		4.7	0.56	5.26
PRODUCT 2X (70%)		113.2	0.2		58.6	0.00	0.00
RINSE NO.2	0.5	7.8	0.1		7.9	0.17	0.79
2.5% CAUSTIC	0.5	6.6	44.7		0.0	0.15	151.84
RINSE NO.3	0.5	5	2.4		0.2	0.11	10.20
					TOTAL	80.66	220.78

EXPERIMENT NUMBER 10 — FEED PLANT STRIPPER PRODUCT (DILUTED 1:3 WITH DI H2O)

CONDITIONS: COND'S pH "ADJUSTED" 9.3; FEED RATE: 12 ML/MIN; COLUMN TEMP 65 DEG C; RESIN DCA-11; D/S

LOADING 13.620 g/L resin — BED VOLUME 100 mls

ISOFLAVONE CONC IN FEED 681.10 PPM

ISOFLAVONE CONC IN FEED 0.091 g/L

BED VOLUMES FED 30 B.V

	Volume (L)	Isoflavone(mg/kg)	D/S(g/kg)	Vol/g	Purity %	Yield %	D/S Accepted					
FEED	2.0	681.1	19		15.6	100.00	100.00	407.2	100.00	216.9	100.00	19
RAFFINATE	2.0	7.6	0.6		1.3	1.12	31.58	1.9	0.47	0.9	0.41	2.1
RINSE NO.1	0.5	62	0.5		1.2	0.14	2.63	0.5	0.03	0.5	0.02	2.7
PRODUCT (35%)	0.5	19078	3.1		64.1	72.06	40.79	1264.2	77.02	562.1	64.79	2.2
PRODUCT 2X (35%)		12241	1.7		60.2	0.00	0.00	647.1	0.00	281.6	0.00	2.2
PRODUCT (70%)	0.5	419.4	0.7		58.9	1.53	3.21	34.24	21.02	5.7	0.66	6.01
PRODUCT 2X (70%)		220.8	0.3		76.9	0.00	0.00	16.72	0.00	0.4	0.00	6.01
RINSE NO.2	0.5	10.7	0.1		18.7	0.43	0.79			33.13	65.86	
2.5% CAUSTIC	0.5	10.1	50.7		0.0	0.00	0.00					
RINSE NO.3	0.5	5	2.4		0.2	0.11	10.20					
					TOTAL	80.81	610.79					

Witnessed and Understood by Me	Date	Recorded/Invented by	Date
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EXPERIMENT NUMBER: 13 FEED: PLANT STRIPPER PRODUCT (DILUTED 1:3 WITH DI H2O)

COND'S: pH "ADJUSTED" 9.3

CONDITIONS: FEED RATE: 12 MLS/MIN

COLUMN TEMP.: 65 DEG C

RESIN: SP-207

D/S

LOADING: 18.078 g/L resin BED VOLUME: 100 mls

ISOFLAVONE CONC. IN FEED: 903.90 PPM

ISOFLAVONE CONC. IN FEED: 0.904 g/L

BED VOLUMES FED: 20 B.V.

	Volume (L)	Isoflavone(mg/kg)	D/S(g/kg)	Vol./g	Purity %	Yield %	D/S Account.
FEED	2.0	903.9	2.1		43.0	100.00	100.00
RAFFINATE	2.0	11.3	0.7		1.6	1.25	33.33
RINSE NO. 1	0.3	13.8	0.4		3.5	0.23	2.86
COMPOSITE (35%)	0.5	3348.4	0.9		372.0	92.61	10.71
PRODUCT 2X (35%)		1738.7	2.7		64.4	0.00	0.00
COMPOSITE (70%)	0.5	147.7	0.6		24.6	4.09	7.14
PRODUCT 2X (70%)		71.3	1.0		7.1	0.00	0.00
RINSE NO. 2	0.3	5.1	0.1		5.1	0.08	0.71
2.5% CAUSTIC	0.3	5.3	64.7		0.0	0.09	258.57
RINSE NO. 3	0.3	4.2	35.6		0.0	0.07	254.29
					TOTAL	98.42	567.62

EXPERIMENT NUMBER: 14 FEED: PLANT STRIPPER PRODUCT (DILUTED 1:3 WITH DI H2O)

COND'S: pH "ADJUSTED" 9.3

CONDITIONS: FEED RATE: 12 MLS/MIN

COLUMN TEMP.: 65 DEG C

RESIN: OPTIPORE

D/S

LOADING: 18.078 g/L resin BED VOLUME: 100 mls

ISOFLAVONE CONC. IN FEED: 903.90 PPM

ISOFLAVONE CONC. IN FEED: 0.904 g/L

BED VOLUMES FED: 20 B.V.

	Volume (L)	Isoflavone(mg/kg)	D/S(g/kg)	Vol./g	Purity %	Yield %	D/S Account.
FEED	2.0	903.9	2.1		43.0	100.00	100.00
RAFFINATE	2.0	3.6	0.5		0.4	0.40	42.86
RINSE NO. 1	0.5	3.7	0.4		0.9	0.08	2.86
COMPOSITE (35%)	0.5	1999.7	3.0		63.0	55.23	35.71
PRODUCT 2X (35%)		924.7	1.3		71.1	0.00	0.00
COMPOSITE (70%)	0.5	1166	1.2		97.2	32.25	14.29
PRODUCT 2X (70%)		635.6	1.3		48.9	0.00	0.00
RINSE NO. 2	0.3	52.1	0.8		6.5	0.66	5.71
2.5% CAUSTIC	0.3	7.7	32.4		0.0	0.15	27.86
RINSE NO. 3	0.3	12.2	86.3		0.0	0.20	616.43
					TOTAL		846.86

Witnessed and Understood by Me	Date	Recorded/Invented by	Date
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ISOFLAVONE HIGH PURITY STEP-WISE ELUTION TESTS

THE PURPOSE OF THESE EXPERIMENTS IS TO:
DETERMINE IF RESINS, (ADS 600,DCA-11 & SP-850) GIVE A HIGHER PURITY PRODUCT FROM PLANT STRIPPER PRODUCT DILUTED WITH DI H2O & pH ADJUSTED UTILIZING A STEP-WISE ELUTION OF 35% ETOH FOLLOWED BY A 70% ELUTION WASHING.

EXPERIMENTAL DATA

DATE: 10/24/01

EXPERIMENT NUMBER: 11

FEED: PLANT STRIPPER PRODUCT (DILUTED 1:3 WITH DI H2O)

COND'S: pH "ADJUSTED" 9.3

CONDITIONS:
FEED RATE: 12 MLS/MIN
COLUMN TEMP.: 65 DEG C
RESIN: ADS 600
0.52 D/S
LOADING: 18.078 g/L resin BED VOLUME: 100 mls
ISOFLAVONE CONC. IN FEED: 903.90 PPM
ISOFLAVONE CONC. IN FEED: 0.904 g/L
BED VOLUMES FED: 20 B.V.

	Volume (L)	Isoflavone(mg/kg)	D/S(g/kg)	Vol/g	Purity %	Yield %	D/S Account.
FEED	2.0	903.9	2.1		43.0	100.00	100.00
RAFFINATE	2.0	19.9	0.6		3.3	2.20	28.57
RINSE NO. 1	0.5	26.7	0.3		2.9	0.44	2.14
COMPOSITE (35%)	0.5	3413.3	4.4		71.4	80.88	52.36
PRODUCT 2X (35%)		1590.6	2.5		63.6	0.00	0.00
COMPOSITE (70%)	0.5	14.4	0.0		0.0	0.40	0.00
PRODUCT 2X (70%)		10.7	0.1		0.0	0.00	0.00
RINSE NO. 2	0.5	6.5	0.0		0.0	0.10	0.00
2.5% CAUSTIC	0.5	5.6	14.1		0.0	0.14	325.71
RINSE NO. 3	0.5	3.7	17.0		0.0	0.06	121.43
					TOTAL	83.22	530.24

EXPERIMENT NUMBER: 12

FEED: PLANT STRIPPER PRODUCT (DILUTED 1:3 WITH DI H2O)

COND'S: pH "ADJUSTED" 9.3

CONDITIONS:
FEED RATE: 12 MLS/MIN
COLUMN TEMP.: 65 DEG C
RESIN: SAFIZA
0.52 D/S
LOADING: 18.078 g/L resin BED VOLUME: 100 mls
ISOFLAVONE CONC. IN FEED: 903.90 PPM
ISOFLAVONE CONC. IN FEED: 0.904 g/L
BED VOLUMES FED: 20 B.V.

	Volume (L)	Isoflavone(mg/kg)	D/S(g/kg)	Vol/g	Purity %	Yield %	D/S Account.
FEED	2.0	903.9	2.1		43.0	100.00	100.00
RAFFINATE	2.0	14.1	0.6		0.7	0.45	28.57
RINSE NO. 1	0.5	5.8	0.2		2.9	0.10	1.43
COMPOSITE (35%)	0.5	6.7	0.0		0.0	0.19	0.00
PRODUCT 2X (35%)		6.6	0.0		0.0	0.00	0.00
COMPOSITE (70%)	0.5	5.9	0.0		0.0	0.11	0.00
PRODUCT 2X (70%)		5.9	0.1		5.9	0.00	0.00
RINSE NO. 2	0.5	4.5	0.2		2.3	0.07	1.43
2.5% CAUSTIC	0.5	12.5	26.3		0.0	0.29	9.29
RINSE NO. 3	0.5	5.1	11.0		0.0	0.08	507.14
					TOTAL	1.04	547.86

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ISOFLAVONE HIGH PURITY STEP WISE ELUTION TESTS

THE PURPOSE OF THESE EXPERIMENTS IS TO:
DETERMINE IF RESINS, (ADS 600,DCA-11 & SP-850) GIVE A HIGHER PURITY PRODUCT FROM PLANT STRIPPER PRODUCT DILUTED WITH DI H20 & pH ADJUSTED UTILIZING A GRADIENT ELUTION OF 35% ETOH FOLLOWED BY A 70% ELUTION WASHING.

EXPERIMENTAL DATA

EXPERIMENT NUMBER: 15 DATE: 10/25/01

FEED: PLANT STRIPPER PRODUCT (DILUTED 1:3 WITH DI H20)

COND'S: pH "ADJUSTED" 9.3

CONDITIONS: FEED RATE: 12 MLS/MIN

COLUMN TEMP.: 65 DEG C

RESIN: ADS 600

D/S

LOADING: 19.636 g/L resin BED VOLUME: 100 mls

ISOFLAVONE CONC. IN FEED: 981.80 PPM

ISOFLAVONE CONC. IN FEED: 0.982 g/L

BED VOLUMES FED: 20 B.V.

	Volume (L)	Isoflavone(mg/kg)	D/S(g/kg)	Vol/g	Purity %	Yield %	D/S Account.
FEED	2.0	981.8	2.0		0.0	100.00	0.0%
RAFFINATE	2.0	23.4	0.0		0.0	2.38	0.0%
RINSE NO.1	0.3	22.5	0.0		0.0	0.35	0.0%
COMPOSITE	0.5	3057.0	1.5		71.1	77.34	0.00
PRODUCT 2X		1130.5	1.4		80.8	0.00	0.00
COMPOSITE	0.5	584.3	0.5		0.0	14.88	0.00
PRODUCT 2X		322.7	0.3		0.0	0.00	0.00
RINSE NO. 2	0.3	45.6	0.0		0.0	0.70	0.00
2.5% CAUSTIC	0.5	33.1	43.7		0.1	0.51	0.00
RINSE NO.3	0.3	14.0	38.9		0.0	0.21	0.00
					TOTAL	96.37	0.00

EXPERIMENT NUMBER: 16 FEED: PLANT STRIPPER PRODUCT (DILUTED 1:3 WITH DI H20)

COND'S: pH "ADJUSTED" 9.3

CONDITIONS: FEED RATE: 12 MLS/MIN

COLUMN TEMP.: 65 DEG.C

RESIN: HP20

D/S

LOADING: 19.636 g/L resin BED VOLUME: 100 mls

ISOFLAVONE CONC. IN FEED: 981.80 PPM

ISOFLAVONE CONC. IN FEED: 0.982 g/L

BED VOLUMES FED: 20 B.V.

	Volume (L)	Isoflavone(mg/kg)	D/S(g/kg)	Vol/g	Purity %	Yield %	D/S Account.
FEED	2.0	981.8	2.0		0.0	100.00	0.00
RAFFINATE	2.0	30.8	0.1		4.4	3.14	0.00
RINSE NO.1	0.3	66.1	0.4		16.5	1.01	0.00
PRODUCT(35%)	0.5	3116.1	2.7		115.4	79.35	0.00
PRODUCT 2X		1181.1	0.0		0.0	0.00	0.00
PRODUCT(70%)	0.5	388.6	0.7		55.7	9.92	0.00
PRODUCT 2X		196.5	0.0		0.0	0.00	0.00
RINSE NO. 2	0.3	12.4	0.4		3.1	0.19	0.00
2.5% CAUSTIC	0.3	16.3	54.6		0.0	0.10	0.00
RINSE NO.3	0.3	0.0	28.0		0.0	0.01	0.00
					TOTAL	93.71	0.00

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EXPERIMENT NUMBER: 17

FEED: PLANT STRIPPER PRODUCT (DILUTED 1:3 WITH DI H2O)
COND'S: pH "ADJUSTED" 9.3

CONDITIONS: FEED RATE: 12 MLS/MIN
COLUMN TEMP.: 65 DEG C
RESIN: XAD7HP

D/S

LOADING: 19.636 g/L resin BED VOLUME: 100 mls
ISOFLAVONE CONC. IN FEED: 981.80 PPM
ISOFLAVONE CONC. IN FEED: 0.982 g/L
BED VOLUMES FED: 20 B.V.

	Volume (L)	Isoflavone(mg/kg)	D/S(g/kg)	Vol./g	Purity %	Yield %	D/S Account.
FEED	2.0	981.8	2.0		49.1	100.00	0.00
RAFFINATE	2.0	37.3	1.1		3.4	3.80	0.00
RINSE NO. 1	0.3	64.3	1.0		6.4	0.98	0.00
PRODUCT(35%)	0.5	2866.4	5.0		57.3	72.99	0.00
PRODUCT 2X		1022	1.8		56.8	0.00	0.00
PRODUCT(70%)	0.5	701.7	1.0		70.2	17.87	0.00
PRODUCT 2X		384.4	0.6		64.3	0.00	0.00
RINSE NO. 2	0.3	94.7	0.4		23.7	1.46	0.00
2.5% CAUSTIC	0.3	183.4	61.7		0.3	2.80	0.00
RINSE NO. 3	0.3	0	0.0		0.0	0.00	0.00
					TOTAL	99.89	0.00

EXPERIMENT NUMBER: 18

FEED: PLANT STRIPPER PRODUCT (DILUTED 1:5 WITH DI H2O)
COND'S: pH "ADJUSTED" 9.3

CONDITIONS: FEED RATE: 12 MLS/MIN
COLUMN TEMP.: 65 DEG C
RESIN: XAD4/1090

D/S

LOADING: 19.636 g/L resin BED VOLUME: 100 mls
ISOFLAVONE CONC. IN FEED: 981.80 PPM
ISOFLAVONE CONC. IN FEED: 0.982 g/L
BED VOLUMES FED: 20 B.V.

	Volume (L)	Isoflavone(mg/kg)	D/S(g/kg)	Vol./g	Purity %	Yield %	D/S Account.
FEED	2.0	981.8	2.0		49.1	100.00	100.00
RAFFINATE	2.0	20.8	33.4		0.1	2.12	1670.00
RINSE NO. 1	0.3	15.1	0.7		2.1	0.23	15.25
PRODUCT(35%)	0.5	3316	3.8		87.5	84.44	47.50
PRODUCT 2X		696.8	1.7		52.8	0.00	0.00
PRODUCT(70%)	0.5	508.5	0.8		63.6	12.95	10.00
PRODUCT 2X		313.4	0.1		313.4	0.00	0.00
RINSE NO. 2	0.3	34.1	0.3		11.4	0.82	2.25
2.5% CAUSTIC	0.3	26.1	61.2		0.0	0.40	271.50
RINSE NO. 3	0.3	11.4	42.4		0.0	0.17	318.00
					TOTAL	100.83	2324.50

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ISOFLAVONE HIGH PURITY STEP-WISE ELUTION TESTS

THE PURPOSE OF THESE EXPERIMENTS IS TO:
DETERMINE IF RESINS, (ADS 600,DCA-11 & SP-850) GIVE A HIGHER PURITY PRODUCT FROM PLANT STRIPPER PRODUCT DILUTED WITH DI H2O & pH ADJUSTED UTILIZING A GRADIENT ELUTION OF 35% ETOH FOLLOWED BY A 70% ELUTION WASHING.

EXPERIMENTAL DATA: DATE: 10/26/01

EXPERIMENT NUMBER: 19 FEED: PLANT STRIPPER PRODUCT (DILUTED 1:3 WITH DI H2O)
COND'S: pH "ADJUSTED" 9.3

CONDITIONS: FEED RATE: 12 MLS/MIN
COLUMN TEMP.: 65 DEG C
RESIN: ADS 600

D/S

LOADING: 18.154 g/L resin BED VOLUME: 100 mls
ISOFLAVONE CONC. IN FEED: 1067.907 PPM
ISOFLAVONE CONC. IN FEED: 1.068 g/L
BED VOLUMES FED: 17 B.V.

	Volume (L)	Isoflavone(mg/kg)	D/S(g/kg)	Vol/g	Purity %	Yield %	D/S Account.
FEED	1.7	1067.9	1.6		66.7	100.00	100.00
RAFFINATE	1.7	23.7	0.6		4.0	2.22	37.50
RINSE NO. 1	0.3	21.9	0.3		7.3	0.36	6.31
COMPOSITE	0.5	2828.8	3.8		80.2	77.91	64.34
PRODUCT 2X		1430.2	1.7		84.1	0.00	0.00
COMPOSITE	0.5	133.8	0.2		66.9	3.69	3.68
PRODUCT 2X		287.4	0.2		143.7	0.00	0.00
RINSE NO. 2	0.3	39.4	0.2		19.7	0.65	2.21
2.5% CAUSTIC	0.3	31.3	51.8		0.1	0.52	270.59
RINSE NO. 3	0.3	4.4	28.9		0.0	0.07	296.69
					TOTAL	85.42	878.31

EXPERIMENT NUMBER: 20 FEED: PLANT STRIPPER PRODUCT (DILUTED 1:3 WITH DI H2O)
COND'S: pH "ADJUSTED" 9.3

CONDITIONS: FEED RATE: 12 MLS/MIN
COLUMN TEMP.: 65 DEG C
RESIN: SP700

D/S

LOADING: 21.358 g/L resin BED VOLUME: 100 mls
ISOFLAVONE CONC. IN FEED: 1067.90 PPM
ISOFLAVONE CONC. IN FEED: 1.068 g/L
BED VOLUMES FED: 20 B.V.

	Volume (L)	Isoflavone(mg/kg)	D/S(g/kg)	Vol/g	Purity %	Yield %	D/S Account.
FEED	2.0	1067.9	1.6		66.7	100.00	100.00
RAFFINATE	2.0	12.3	0.6		2.1	1.15	37.50
RINSE NO. 1	0.3	17.3	0.4		4.3	0.24	3.75
PRODUCT(35%)	0.5	3892.2	5.8		67.1	91.12	90.63
PRODUCT 2X		1979.4	2.8		70.7	0.00	0.00
PRODUCT(70%)	0.5	460.4	0.5		92.1	10.78	7.81
PRODUCT 2X		222.8	0.2		111.4	0.00	0.00
RINSE NO. 2	0.3	39.3	0.1		39.3	0.55	0.94
2.5% CAUSTIC	0.3	37.8	39.9		0.1	0.53	14.69
RINSE NO.3	0.3	4.3	27.6		0.0	0.06	258.75
					TOTAL	104.01	514.06

Witnessed and Understood by Me	Date	Recorded/Invented by	Date
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ISOFLAVONE HIGH PURITY LOADING VS. PERFORMANCE TESTS

THE PURPOSE OF THESE EXPERIMENTS IS TO:
DETERMINE IF A VARIANCE IN THE LOADING BED VOLUME OF AD9600 GIVES A HIGHER PURITY PRODUCT

EXPERIMENTAL DATA

EXPERIMENT NUMBER: 31

DATE: 10/3V01
FEED: PLANT STRIPPER PRODUCT (DILUTED 1:3 WITH DI H2O)
COND'S: pH "ADJUSTED" 9.3

CONDITIONS:
FEED RATE: 12 MLS/MIN
COLUMN TEMP.: 65 DEG C
RESIN: AD9600
COLUMN NO.: 1

LOADING: 7.9 g/L resin
ISOFLAVONE CONC. IN FEED: 785.1 PPM
ISOFLAVONE CONC. IN FEED: 0.79 g/L
BED VOLUMES FED: 10 B.V.
BED VOLUME: 100 mls

	Volume (L)	Isoflavone(mg/kg)	D/S(g/kg)	Vol/g	Purity %	Yield %	D/S Account.
COLUMN FEED	1.0	785.1	1.6		49.1	100.0	100.0
RAFFINATE	1	16.4	0.9		1.8	2.1	56.3
RINSE NO. 1	0.3	17.0	0.0		0.0	0.6	0.0
PRODUCT (35%)	0.5	1804.9	1.9		95.0	114.9	59.4
PRODUCT 2X (35%)		908.6	0.9		100.0	0.0	0.0
PRODUCT (70%)	0.5	6.7	0.0		0.0	0.4	0.0
PRODUCT 2X (70%)		4.7	0.0		0.0	0.0	0.0
RINSE NO. 2	0.3	0.7	0.0		0.0	0.0	0.0
NaOH	0.3	2.4	63.9		0.0	0.1	704.4
RINSE NO. 3	0.3	1.8	5.5		0.0	0.1	99.4
					TOTAL	118.3	919.4

EXPERIMENTAL DATA

EXPERIMENT NUMBER: 32

DATE: 10/3V01
FEED: PLANT STRIPPER PRODUCT (DILUTED 1:3 WITH DI H2O)
COND'S: pH "ADJUSTED" 9.3

CONDITIONS:
FEED RATE: 12 MLS/MIN
COLUMN TEMP.: 65 DEG C
RESIN: AD9600
COLUMN NO.: 1

LOADING: 15.7 g/L resin
ISOFLAVONE CONC. IN FEED: 785.1 PPM
ISOFLAVONE CONC. IN FEED: 0.79 g/L
BED VOLUMES FED: 20 B.V.
BED VOLUME: 100 mls

	Volume (L)	Isoflavone(mg/kg)	D/S(g/kg)	Vol/g	Purity %	Yield %	D/S Account.
COLUMN FEED	2.0	785.1	1.6		49.1	100.0	100.0
RAFFINATE	2	24.9	0.5		1.5	3.2	31.3
RINSE NO. 1	0.3	38.1	0.2		19.0	0.7	1.9
PRODUCT (35%)	0.5	3159.6	3.7		85.4	100.6	57.8
PRODUCT 2X (35%)		1563.6	1.6		97.7	0.0	0.0
PRODUCT (70%)	0.5	180.5	0.1		180.5	5.7	1.6
PRODUCT 2X (70%)		104.6	0.2		52.3	0.0	0.0
RINSE NO. 2	0.3	7.1	0.1		7.1	0.1	0.9
NaOH	0.3	3.0	141.7		0.0	0.1	131.6
RINSE NO. 3	0.3	15.4	19.6		0.1	0.5	183.2
					TOTAL	110.7	408.8

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Witnessed and Understood by Me	Date	Recorded/Invented by	Date
	4/20/04	[redacted]	[redacted]